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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BOSWORTH, KAMI A	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,318	BRUCKER ET AL.	
	Examiner	Art Unit	
	KAMI A. BOSWORTH	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 23 March 2009.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 and 84-121 is/are pending in the application.

4a) Of the above claim(s) 84-121 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-77 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 23 March 2009 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is responsive to the amendment filed on 3/23/2009. As directed by the amendment: claims 7, 10, 27, 28, 51, 54, 61-63, and 66-69 have been amended, claims 78-83 have been cancelled, and claims 84-121 remain withdrawn. Thus, claims 1-77 are presently pending in this application.

Claim Objections

2. Claim 54 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 54 is directly dependent on claim 51; however, both claims 51 and 54 recite "wherein a size of said opening at said apex in an absence of fluid pressure is approximately in the range of 0.220 mm to 0.260 mm".

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

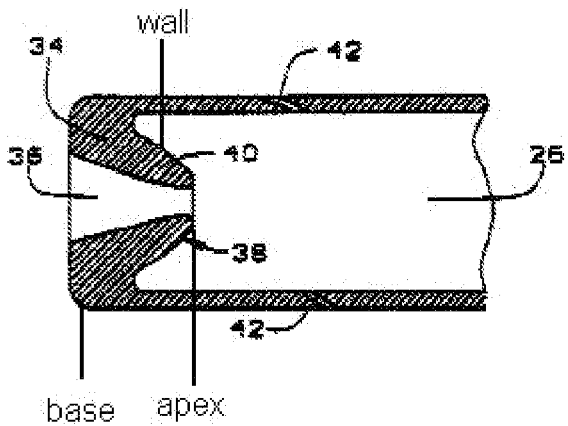
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay (US Pat 5,616,137) in view of Stevens et al. (US Pat 5,916,193).

5. Re claim 63, Lindsay discloses a catheter assembly 20 (Fig 1) for introducing fluid into a vessel (Col 1, Lines 10-12), the catheter assembly comprising a restrictor 38 (Fig 6) at a distal end thereof, said restrictor comprising: a circular base portion (best seen in Fig A below) formed approximate a distal end of said restrictor; and a conical wall portion 40 (best seen in Fig A below) extending in a proximal direction (as seen in Fig 6) from said circular base portion to an apex thereof, said apex defining an opening 36 (Fig 6). Lindsay does not disclose that the conical wall portion is flexible or that the size of the opening generally decreases as said conical wall portion flattens out distally as pressure of the fluid within said restrictor increases. Stevens et al., however, teaches a conically-shaped valve 660 (Fig 4J) comprising flexible conical wall portions 662 (Fig 4H) that generally decreases a size of an opening (formed by conical wall portions 662, Fig 4J) as said conical wall portion flattens out distally as pressure of the fluid within said restrictor increases (Col 14, Lines 63-66) for the purpose of limiting flow out of the valve (Col 14, Lines 66-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay to include a flexible conical wall portion that generally decreases a size of an opening as pressure increases, as taught by Stevens et al., for the purpose of limiting flow out of the valve

(Col 14, Lines 66-67).

Fig. A



6. Re claim 64, Lindsay discloses that said conical wall portion decreases in thickness in the proximal direction from said circular base portion to said apex (as seen in Fig 6).

7. Re claim 65, Lindsay/Stevens et al. discloses all of the claimed features except that a size of the opening ranges from approximately 0.889 mm at the circular base portion to approximately 0.1016 mm at the apex in absence of fluid pressure. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the base of the opening to be approximately 0.889 mm and the apex of the opening to be approximately 0.1016, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

8. Re claim 66, Lindsay/Stevens et al. disclose all the claimed features except that the size of the opening at the apex in an absence of fluid pressure is approximately in the range of 0.220 mm and 0.260 mm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the opening of the apex in an absence of fluid pressure to have a size in the range of 0.220 mm and 0.260 mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

9. Re claim 67, Lindsay/Stevens et al. discloses all of the claimed features except that a size of the opening of the conical wall portion between and absence of pressure and a maximum pressure within the restrictor ranges approximately from 0.0762 mm to 0.127 mm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the opening of the conical wall portion to change so that between an absence of pressure and a maximum pressure, the tip ranges approximately from 0.0762 mm to 0.127 mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

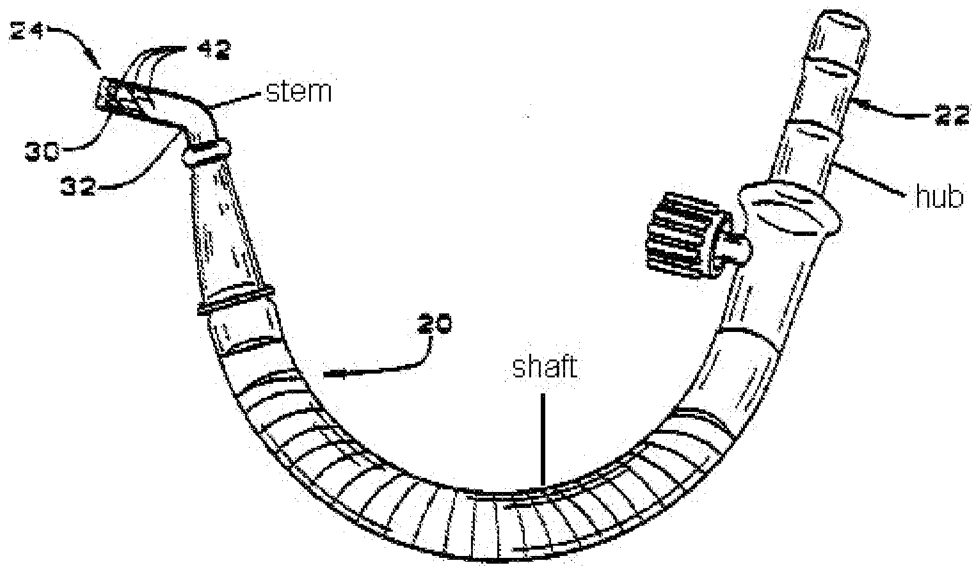
10. Claims 1, 2, 3, 6-18, 22, 24, 25, 29-32, 37-40, 46, 47, 50-59, and 68-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay (US Pat 5,616,137) in view of Stevens et al. (US Pat 5,916,193) and Savage et al. (WO 01/51116).

11. Re claim 1, Lindsay discloses a catheter assembly 20 (Fig 1) for introducing fluid into a vessel (Col 1, Lines 10-12), the catheter assembly comprising: a shaft (best seen in Fig B below); a hub 28 (Col 2, Line 37) affixed to a proximal end of said shaft; a stem 30 (Fig 1) affixed to a distal end of said shaft, said stem having a porous section (defined by microholes 42, Fig 1) approximate a distal end thereof, said porous section defining a plurality of microholes 42 (Fig 1) generally distributed uniformly thereabout and inclined by a predetermined angle (Col 3, Lines 8-9) in a proximal direction; and a tip 34 (Fig 6) affixed to said distal end of said stem, said tip including a conically-shaped valve 40 (Fig 6) with an apex (best seen in Fig A above) thereof defining an opening 36 (Fig 6) and pointing in the proximal direction (as seen in Fig 6) such that as the fluid flow within said catheter assembly and pressure increases within said tip, said conically-shaped valve dynamically changes (Col 3, Line 48-50) and the amount of the fluid flowing out of said microholes of said stem increases (Col 3, Lines 48-53). Lindsay does not disclose that said conically-shaped valve generally decreases a size of said opening so that the amount of the fluid flowing out of said opening of said tip decreases; nor does Lindsay disclose that the forces of the fluid flowing out of said microholes and said opening substantially balance thereby enabling a position of said tip and said stem within the vessel to remain stable while fluid is finely dispersed therefrom. Stevens et al., however, teaches a conically-shaped valve 660 (Fig 4J) that generally decreases a size of an opening (formed by leaflets 662, Fig 4J) as pressure increases so that the amount of the fluid flowing out of said opening of said tip decreases (Col 14, Lines 63-66) for the purpose of limiting flow out of the valve (Col 14, Lines 66-67). Therefore, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay to include a conically-shaped valve that generally decreases a size of an opening as pressure increases, as taught by Stevens et al., for the purpose of limiting flow out of the valve (Col 14, Lines 66-67). Furthermore, Savage et al. teaches that as fluid flows within a catheter assembly 10 (Fig 1) and pressure increases within a tip 20 (Fig 1), the forces of the fluid flowing out of microholes 42 (Fig 2) and an opening 44 (Fig 2) substantially balance thereby enabling a position of said tip and said stem within the vessel to remain stable while fluid is finely dispersed therefrom (Page 9, Lines 27-29) for the purpose of eliminating movement of the catheter during injection (Page 9, Lines 30-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Savage et al. to include microholes and an opening that substantially balance each other and enable the tip and stem to remain stable while fluid is dispersed therefrom, as taught by Savage et al., for the purpose of

eliminating movement of the catheter during injection (Page 9, Lines 30-31).

Fig. B



12. Re claim 29, Lindsay discloses a catheter assembly 20 (Fig 1) for introducing fluid into a vessel (Col 1, Lines 10-12), the catheter assembly comprising: a stem 30 (Fig 1) having approximate a distal end thereof a porous section defining a plurality of microholes 42 (Fig 1) distributed thereabout and inclined by a predetermined angle (Col 3, Lines 8-9) in a proximal direction; and a tip 34 (Fig 6) affixed to said distal end of said stem, said tip including a conically-shaped valve 40 (Fig 6) with an apex (best seen in Fig A above) thereof pointing in the proximal direction (as seen in Fig 6) and defining an opening 36 (Fig 6), said conically-shaped valve dynamically changes as pressure of the fluid within said tip increases (Col 3, Line 48-50). Lindsay does not disclose that the size of the opening generally decreases as pressure of the fluid within said tip increases or that the forces of the fluid flowing from within said catheter assembly out of said

opening of said tip and out of said microholes of said stem substantially balance thereby substantially eliminating both recoil and whipping of said catheter assembly thus enabling a position thereof within the vessel to remain stable while the fluid is finely dispersed therefrom. Stevens et al., however, teaches a conically-shaped valve 660 (Fig 4J) that generally decreases a size of an opening (formed by leaflets 662, Fig 4J) as pressure increases (Col 14, Lines 63-66) for the purpose of limiting flow out of the valve (Col 14, Lines 66-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay to include a conically-shaped valve that generally decreases a size of an opening as pressure increases, as taught by Stevens et al., for the purpose of limiting flow out of the valve (Col 14, Lines 66-67). Furthermore, Savage et al. teaches that the forces of the fluid flowing from within a catheter assembly 10 (Fig 1) out of an opening 44 (Fig 1) of a tip 20 (Fig 1) and out of microholes 42 (Fig 2) of a stem 16 (Fig 1) substantially balance thereby substantially eliminating both recoil and whipping of said catheter assembly thus enabling a position thereof within the vessel to remain stable while the fluid is finely dispersed therefrom (Page 9, Lines 27-31) for the purpose of eliminating movement of the catheter during injection (Page 9, Lines 30-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay to include microholes and an opening that substantially balance each other to eliminate recoil and whipping to remain stable while fluid is dispersed therefrom, as taught by Savage et al., for the purpose of eliminating movement of the catheter during injection (Page 9, Lines 30-31).

13. Re claim 70, Lindsay discloses a catheter assembly 20 (Fig 1) for introducing fluid into a vessel (Col 1, Lines 10-12), said catheter assembly comprising: a stem 30 (Fig 1) having approximate a distal end thereof a porous section defining a plurality of microholes 42 (Fig 1) distributed thereabout and inclined by a predetermined angle (Col 3, Lines 8-9) in a proximal direction; and a restrictor 38 (Fig 6) affixed to said distal end of said stem, said restrictor defining an opening 36 (Fig 6). Lindsay does not disclose that the size of the opening generally decreases as pressure of the fluid within said restrictor increases; nor does Lindsay disclose that the forces of the fluid flowing from within said catheter assembly out of said opening of said restrictor and out of said microholes of said stem substantially balance to prevent axial and radial movement of said catheter assembly thus enabling a position thereof within the vessel to remain stable while the fluid is finely dispersed therefrom in a cloud-like form. Stevens et al., however, teaches a conically-shaped valve 660 (Fig 4J) that generally decreases a size of an opening (formed by leaflets 662, Fig 4J) as pressure increases (Col 14, Lines 63-66) for the purpose of limiting flow out of the valve (Col 14, Lines 66-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay to include a conically-shaped valve that generally decreases a size of an opening as pressure increases, as taught by Stevens et al., for the purpose of limiting flow out of the valve (Col 14, Lines 66-67). Furthermore, Savage et al. teaches that the forces of the fluid flowing from within a catheter assembly 10 (Fig 1) out of an opening 44 (Fig 1) of a restrictor 18 (Fig 1) and out of microholes 42 (Fig 2) of a stem 16 (Fig 1) substantially balance to prevent axial and radial movement of said catheter

assembly thus enabling a position thereof within the vessel to remain stable while the fluid is finely dispersed therefrom (Page 9, Lines 27-29) for the purpose of eliminating movement of the catheter during injection (Page 9, Lines 30-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay to include microholes and an opening that substantially balance to prevent axial and radial movement of said catheter assembly while fluid is dispersed therefrom, as taught by Savage et al., for the purpose of eliminating movement of the catheter during injection (Page 9, Lines 30-31).

14. Re claims 2 and 46, Lindsay/Stevens et al. disclose all the claimed features except that the outer part of said tip is made of nylon in a range approximately from 25D nylon to 55D nylon. Savage et al., however, teaches the use of 55D nylon (Page 7, Lines 30-31) for the purpose of forming a catheter with a hardness that facilitates use within the body (Page 7, Line 31). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include a tip made of a material of approximately 25D nylon to 55D nylon, as taught by Savage et al., for the purpose of forming a catheter with a hardness that facilitates use within the body (Page 7, Line 31). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tip of 25D nylon to 55D nylon, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

15. Re claims 3 and 47, Lindsay/Stevens et al. disclose all the claimed features except that the outer part of said tip is made of 35D nylon. Savage et al., however, teaches the use of nylon (Page 7, Line 30) and a material having a durometer of 35D (Page 10, Line 28) for the purpose of forming a flexible tip section (Page 10, Lines 26-28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include an outer tip of 35D nylon, as taught by Savage et al., for the purpose of forming a flexible tip section (Page 10, Lines 26-28). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the outer part of the tip from nylon having a hardness of 35D, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

16. Re claims 6 and 50, Lindsay/Stevens et al. discloses all of the claimed features except that a size of the opening of the conically-shaped valve ranges approximately from 0.889 mm at a base thereof to 0.1016 mm at the apex in absence of fluid pressure. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the base of the opening to be approximately 0.889 mm and the apex of the opening to be approximately 0.1016, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

17. Re claims 7, 10, 51, and 54, Lindsay/Stevens et al. disclose all the claimed features except that the size of the opening at the apex in an absence of fluid pressure

is approximately in the range of 0.220 mm and 0.260 mm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the opening of the apex to have a size in the range of 0.220 mm and 0.260 mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

18. Re claim 8, Lindsay discloses that said conically-shaped valve includes a circular base portion (best seen in Fig A above) affixed to approximately a distal end of said tip; and a conical wall portion 38 (best seen in Fig A above) extending and decreasing in thickness (as seen in Fig 6) from said circular base portion to said apex.

19. Re claims 9 and 53, Lindsay/Stevens et al. discloses all of the claimed features except that a size of the opening of the tip ranges approximately from 0.889 mm at a base thereof to 0.1016 mm at the apex in absence of fluid pressure. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the base of the opening to be approximately 0.889 mm and the apex of the opening to be approximately 0.1016, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

20. Re claims 11 and 55, Lindsay/Stevens et al. disclose the size of the opening of the conically-shaped valve changes with the introduction of pressure (Col 14, Lines 63-66) but does not disclose that the size of the opening of the conically-shaped valve between an absence of pressure and a maximum pressure within said tip ranges

approximately from 0.0762 mm to 0.127 mm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the opening of the valve to change so that between an absence of pressure and a maximum pressure, the tip ranges approximately from 0.0762 mm to 0.127 mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

21. Re claims 12 and 56, Lindsay/Stevens et al. disclose all the claimed features except that a difference is a size of the opening of the conically-shaped valve between an absence of pressure and a maximum pressure depends on at least one of a shape of said valve and a thickness of a wall portion of said valve. Savage et al., however, teaches that a difference is a size of an opening 44 (Fig 2) of the valve 18 (Fig 2) between an absence of pressure and a maximum pressure depends on the shape of the valve (Page 10, Lines 26-33) for the purpose of obtaining the desired expansion under normal ranges of operating flow rates (Page 10, Lines 29-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include a valve whose opening between an absence of pressure and a maximum pressure depends on the shape of the valve, as taught by Savage et al., for the purpose of obtaining the desired expansion under normal ranges of operating flow rates (Page 10, Lines 29-30).

22. Re claims 13 and 57, Lindsay/Stevens et al. disclose all the claimed features except that the conically-shaped valve is made of a material sufficiently pliable to enable

passage of a guidewire therethrough but to avoid everting under the pressure extant within said tip. Savage et al., however, teaches that valve 18 (Fig 2) is made of a material sufficiently pliable to enable passage of a guidewire therethrough but to avoid everting under the pressure extant within said tip (Page 10, Lines 6-12) for the purpose of guiding the catheter to a target site (Page 14, Lines 14-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include a valve made of a material sufficiently pliable to enable passage of a guidewire therethrough but to avoid everting under the pressure extant within said tip, as taught by Savage et al., for the purpose of guiding a catheter to a target site (Page 14, Lines 14-15).

23. Re claims 14 and 30, Lindsay/Stevens et al. disclose all the claimed features except that the stem is made of nylon in a range approximately from 45D nylon to 75D nylon. Savage et al., however, teaches the use of 50D nylon to 60D nylon (Page 7, Lines 30-31) for the purpose of forming a catheter with a hardness that facilitates use within the body (Page 7, Line 31). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include a stem made of nylon in the range of approximately 45D nylon to 75D nylon, as taught by Savage et al., for the purpose of forming a catheter with a hardness that facilitates use within the body (Page 7, Line 31). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stem of 45D nylon to 75D nylon, since it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

24. Re claims 15 and 31, Lindsay/Stevens et al. disclose all the claimed features except that the stem is made of 63D nylon. Savage et al., however, teaches the use of 63D nylon (*approximately* 50D to 60D nylon, Page 10, Line 28) for the purpose of forming a catheter with a hardness that facilitates use within the body (Page 7, Line 31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include an stem of 63D nylon, as taught by Savage et al., for the purpose of forming a flexible tip section (Page 10, Lines 26-28). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stem from nylon having a hardness of 63D, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

25. Re claims 16 and 37, Lindsay/Stevens et al. disclose all the claimed features except that said predetermined angle depends on at least one of a size of said catheter assembly, a shape of said catheter assembly, a desired volume of the fluid to be introduced into the vessel, and a ratio of an amount of the fluid to be flowing out of said microholes to that to be flowing out of said opening. Savage et al., however, teaches that the predetermined angle of micropores 42 (Fig 2) depends on the size and shape of the catheter assembly (Page 11, Lines 30-31) for the purpose of ensuring that fluid flow forces are substantially balanced (Page 12, Lines 25-26). Therefore, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include microholes having a predetermined angle depending on the size and shape of the catheter assembly, as taught by Savage et al., for the purpose of ensuring that fluid flow forces are substantially balanced (Page 12, Lines 25-26).

26. Re claims 17 and 38, Lindsay/Stevens et al. disclose all the claimed features except that said predetermined angle by which said microholes of said porous section are inclined ranges approximately from 0 to 45 degrees. Savage et al., however, teaches that the predetermined angle by which microholes 42 (Fig 2) of said porous section are included ranges *approximately* from 0 to 45 degrees (Page 11, Lines 30-31) for the purpose of ensuring that fluid flow forces are substantially balanced (Page 12, Lines 25-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include microholes inclined within the range of approximately 0 to 45 degrees, as taught by Savage et al., for the purpose of ensuring that fluid flow forces are substantially balanced (Page 12, Lines 25-26). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the microholes at predetermined angles ranging approximately from 0 to 45 degrees since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

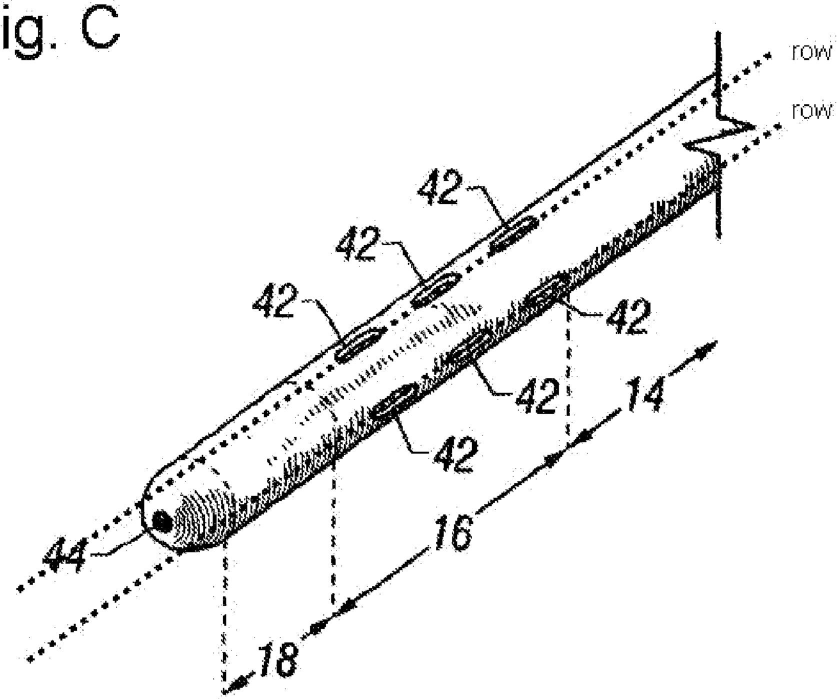
27. Re claims 18 and 39, Lindsay/Stevens et al. disclose all the claimed features except that the predetermined angle by which said microholes of said porous section is

included is approximately 20 degrees. Savage et al., however, teaches that the predetermined angle by which microholes 42 (Fig 2) of said porous section are included is *approximately* 20 degrees (Page 11, Line 28) for the purpose of ensuring that fluid flow forces are substantially balanced (Page 12, Lines 25-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include microholes inclined at approximately 20 degrees, as taught by Savage et al., for the purpose of ensuring that fluid flow forces are substantially balanced (Page 12, Lines 25-26). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the microholes at predetermined angles of approximately 20 degrees since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

28. Re claims 22 and 32, Lindsay/Stevens et al. disclose all the claimed features except that microholes are distributed about said porous section according to a pattern having a plurality of pairs of longitudinally arranged rows, with each of said rows being laterally spaced generally equidistantly from its neighbors. Savage et al., however, teaches that microholes 42 (Fig 2) are distributed about said porous section according to a pattern having a plurality of pairs of longitudinally arranged rows (best seen in Fig C below) with each of said row pairs being laterally spaced generally equidistantly from its neighbors (as seen in Fig C below; Page 12, Lines 3-4) for the purpose of ensuring a substantial cancellation of the fluid force vectors (Page 11, Lines 5-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was

made to modify Lindsay/Stevens et al. to include microholes arranged into a plurality of pairs of longitudinally arranged rows spaced equidistantly from each other, as taught by Savage et al., for the purpose of ensuring a substantial cancellation of the fluid force vectors (Page 11, Lines 5-7).

Fig. C



29. Re claims 24 and 58, Lindsay/Stevens et al. disclose all the claimed features except that the catheter assembly is for use with a guidewire. Savage et al., however, teaches that the catheter assembly is for use with a guidewire (Page 10, Line 6) for the purpose of guiding the catheter to a target site (Page 14, Lines 14-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include a guidewire, as taught by Savage et al., for the purpose of guiding a catheter to a target site (Page 14, Lines 14-15).

30. Re claims 25 and 59, Lindsay/Stevens et al. disclose all the claimed features except that the catheter assembly permits measurement of pressure extant in the vessel. Savage et al., however, teaches that the catheter assembly permits measurement of pressure extant in the vessel (Page 10, Lines 2-5) for the purpose of monitoring the fluid flow out of the catheter (Page 10, Line 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include an assembly that permits measurement of pressure extant in the vessel, as taught by Savage et al., for the purpose of monitoring the fluid flow out of the catheter (Page 10, Line 4).

31. Re claim 40, Lindsay discloses all the claimed features except that the predetermined angel by which the microholes of the porous section are inclined is approximately 0 degrees. Stevens et al., however, teaches microholes 666 (Fig 4J) perpendicular to the central axis (and thus being inclined at approximately 0 degrees; Fig 4J) for the purpose of providing flow ports to the catheter (Col 15, Lines 8-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay to include microholes inclined at approximately 0 degrees, as taught by Stevens et al., for the purpose of providing flow ports to the catheter (Col 15, Lines 8-9).

32. Re claim 52, Lindsay discloses that said conically-shaped valve includes: a circular base portion (best seen in Fig A above) affixed to approximately a distal end of said tip; and a conical wall portion (best seen in Fig A above) extending and decreasing in thickness (as seen in Fig 6) from said circular base portion to said apex.

33. Re claim 68, Lindsay/Stevens et al. disclose all the claimed features except that a difference is a size of the opening of the conical wall portion between an absence of pressure and a maximum pressure depends on at least one of a shape of said valve and a thickness of said conical wall portion. Savage et al., however, teaches that a difference is a size of an opening 44 (Fig 2) of a valve 18 (Fig 2) between an absence of pressure and a maximum pressure depends on the shape of the valve (Page 10, Lines 26-33) for the purpose of obtaining the desired expansion under normal ranges of operating flow rates (Page 10, Lines 29-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include a valve whose opening between an absence of pressure and a maximum pressure depends on the shape of the valve, as taught by Savage et al., for the purpose of obtaining the desired expansion under normal ranges of operating flow rates (Page 10, Lines 29-30).

34. Re claim 69, Lindsay/Stevens disclose all the claimed features except that the conical wall portion is made of a material sufficiently pliable to enable passage of a guidewire therethrough but to avoid everting under the pressure extant within said restrictor. Savage et al., however, teaches that valve 18 (Fig 2) is made of a material sufficiently pliable to enable passage of a guidewire therethrough but to avoid everting under the pressure extant within said restrictor (Page 10, Lines 6-12) for the purpose of guiding the catheter to a target site (Page 14, Lines 14-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include a valve made of a material sufficiently pliable to

enable passage of a guidewire therethrough but to avoid everting under the pressure extant within said restrictor, as taught by Savage et al., for the purpose of guiding a catheter to a target site (Page 14, Lines 14-15).

35. Re claim 71, Lindsay/Stevens et al. disclose all the claimed features except that the microholes are generally distributed uniformly about the porous section both longitudinally along an axis thereof and radially about a circumference thereof. Savage et al., however, teaches that microholes 42 (Fig 2) are generally distributed uniformly about said porous section both longitudinally along an axis thereof and radially about a circumference thereof (as seen in Fig 2) for the purpose of ensuring a substantial cancellation of the fluid force vectors (Page 11, Lines 5-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include microholes generally distributed uniformly longitudinally and radially about the porous section, as taught by Savage et al., for the purpose of ensuring a substantial cancellation of the fluid force vectors (Page 11, Lines 5-7).

36. Re claim 72, Lindsay/Stevens et al. disclose all the claimed features except that microholes are distributed about said porous section according to a pattern having a plurality of pairs of longitudinally arranged rows, with each of said rows being laterally spaced generally equidistantly from its neighbors. Savage et al., however, teaches that microholes 42 (Fig 2) are distributed about said porous section according to a pattern having a plurality of pairs of longitudinally arranged rows (best seen in Fig C above) with each of said row pairs being laterally spaced generally equidistantly from its neighbors

(as seen in Fig C above; Page 12, Lines 3-4) for the purpose of ensuring a substantial cancellation of the fluid force vectors (Page 11, Lines 5-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include microholes arranged into a plurality of pairs of longitudinally arranged rows spaced equidistantly from each other, as taught by Savage et al., for the purpose of ensuring a substantial cancellation of the fluid force vectors (Page 11, Lines 5-7).

37. Re claim 73, Lindsay/Stevens et al. disclose all the claimed features except that the predetermined angle by which said microholes of said porous section is included is approximately 20 degrees. Savage et al., however, teaches that the predetermined angle by which microholes 42 (Fig 2) of said porous section are included is *approximately* 20 degrees (Page 11, Line 28) for the purpose of ensuring that fluid flow forces are substantially balanced (Page 12, Lines 25-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al. to include microholes inclined at approximately 20 degrees, as taught by Savage et al., for the purpose of ensuring that fluid flow forces are substantially balanced (Page 12, Lines 25-26). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the microholes at predetermined angles of approximately 20 degrees since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

38. Claims 4, 5, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay (US pat 5,616,137)/Stevens et al. (US Pat 5,916,193)/Savage et al. (WO 01/51116) in view of Eldor (US Pat 5,800,407).

39. Re claims 4 and 48, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the length of the tip range approximately from 1 mm to 10 mm. Eldor, however, teaches that the length of the tip (the portion prior to the porous section) is 1 mm (Col 2, Lines 54-57) for the purpose of providing a desired stream of fluid (Col 4, Lines 40-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include a tip having a length in the range of approximately 1 mm to 10 mm, as taught by Eldor, for the purpose of providing a desired stream of fluid (Col 4, Lines 40-42). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tip have a length in the range of approximately 1 mm to 10 mm since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

40. Re claims 5 and 49, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that length of said tip ranges approximately 1 mm to 2 mm. Eldor, however, teaches that the length of the tip (the portion prior to the porous section) is 1 mm (Col 2, Lines 54-57) for the purpose of providing a desired stream of fluid (Col 4, Lines 40-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to

include a tip having a length in the range of approximately 1 mm to 2 mm, as taught by Eldor, for the purpose of providing a desired stream of fluid (Col 4, Lines 40-42). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tip have a length in the range of approximately 1 mm to 2 mm since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

41. Claims 27, 28, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US pat 5,616,137)/Stevens et al. (US Pat 5,916,193)/Savage et al. (WO 01/51116) in view of Nilsson et al. (US Pat 6,132,405).

42. Re claims 27 and 61, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that a ratio of the fluid flowing out of said opening to that out of said microholes is approximately 25% to 75%, respectively, when the pressure of the fluid has flattened out said conically-shaped valve. Nilsson et al., however, teaches that a ratio of the fluid flowing out of an opening 17 (Fig 3) to that out of microholes 16, 21, 22 (Fig 3) is approximately 25% to 75%, respectively (Col 2, Lines 52-55) for the purpose of reducing the chance that the catheter will move to a large degree (Col 5, Lines 10-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include a opening in which 25% of the fluid flows outward along with microholes in which 75% of the fluid flows outward, as taught by Nilsson et al., for the purpose of reducing the chance that the catheter will move to a large degree (Col 5, Lines 10-14).

43. Re claims 28 and 62, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that a ratio of the fluid flowing out of said opening to that out of said microholes is between approximately 10% to 90%, respectively, and 49% to 51%, respectively, when the pressure of the fluid has flattened out said conically-shaped valve. Nilsson et al., however, teaches that a ratio of the fluid flowing out of an opening 17 (Fig 3) to that out of microholes 16, 21, 22 (Fig 3) is approximately 25% to 75%, respectively (Col 2, Lines 52-55) for the purpose of reducing the chance that the catheter will move to a large degree (Col 5, Lines 10-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include an opening and microholes through with fluid flow has a ratio between approximately 10% to 90% and 49% to 51%, as taught by Nilsson et al., for the purpose of reducing the chance that the catheter will move to a large degree (Col 5, Lines 10-14).

44. Claims 19, 20, 21, 23, and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US pat 5,616,137)/Stevens et al. (US Pat 5,916,193)/Savage et al. (WO 01/51116) in view of Schwartz et al. (PG PUB 2003/0009132).

45. Re claims 19 and 41, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the predetermined angle by which said microholes of said porous section is inclined changes with position along the stem. Schwartz et al., however, teaches that the predetermined angle α (Fig 10) by which microholes 66 (Fig 10) of the porous section is inclined change with position along stem 60 (as seen in Fig 10; Para 100, Lines 13-17) for the purpose of creating a large cloud of dispersed fluid

(Para 100, Line 13). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include microholes with changing angles of inclination along the stem, as taught by Schwartz et al., for the purpose of creating a large cloud of dispersed fluid (Para 100, Line 13).

46. Re claims 20 and 42, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the size of the microholes is in a range approximately from 5 microns to 250 microns. Schwartz et al., however, teaches the use of microholes having a size in a range *approximately* from 5 microns to 250 microns (0.002” to 0.008”; Para 95, Lines 10-11) for the purpose of forming a cloud of dispersed fluid (Para 95, Line 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include microholes having a size in the range of approximately 5 microns to 250 microns, as taught by Schwartz et al., for the purpose of forming a cloud of dispersed fluid (Para 95, Line 8). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include microholes having a size within the range of approximately 5 microns to 250 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

47. Re claims 21 and 43, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the size of the microholes is approximately 50 microns. Schwartz et al., however, teaches the use of microholes having a size of approximately

50 microns (0.002”; Para 95, Lines 10-11) for the purpose of forming a cloud of dispersed fluid (Para 95, Line 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include microholes having a size of approximately 50 microns, as taught by Schwartz et al., for the purpose of forming a cloud of dispersed fluid (Para 95, Line 8). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create microholes of approximately 50 microns in size since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

48. Re claims 23 and 45, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the diameter of the microholes of the porous section changes with position along the stem. Schwartz et al., however, teaches microholes 66 (Fig 6) having a diameter than changes with position along a stem 60 (as seen in Fig 6; Para 96, Lines 1-2) for the purpose of creating a pressure gradient which results in a relatively uniform cloud shape (Para 96, Lines 2-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include microholes that have diameters that changes with position along the stem, as taught by Schwartz et al., for the purpose of creating a pressure gradient which results in a relatively uniform cloud shape (Para 96, Lines 2-4).

49. Re claim 44, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the size of the microholes is approximately 100 microns. Schwartz et al., however, teaches the use of microholes having a size of approximately 100 microns (0.0047"; Para 97, Lines 10-11) for the purpose of forming a cloud of dispersed fluid (Para 95, Line 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include microholes having a size of approximately 100 microns, as taught by Schwartz et al., for the purpose of forming a cloud of dispersed fluid (Para 95, Line 8). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create microholes of approximately 100 microns in size since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

50. Claims 26 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US pat 5,616,137)/Stevens et al. (US Pat 5,916,193)/Savage et al. (WO 01/51116) in view of Klima et al. (US Pat 6,290,692).

51. Re claim 26, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except a strain relief element interconnected between the hub and proximal end of the shaft. Klima et al., however, teaches a strain relief element 22 (Fig 1) interconnected between a hub 16 (Fig 1) and a proximal end of a shaft 20 (Fig 1) for the purpose of providing a connection between the hub and the shaft (Col 2, Line 47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify Lindsay/Stevens et al./Savage et al. to include a strain relief element, as taught by Klima et al., for the purpose of connecting the hub and shaft (Col 2, Line 47).

52. Re claim 60, Lindsay discloses a shaft (best seen in Fig B above) affixed to a proximal end of the stem and a hub 28 (Col 2, Line 37) but does not disclose a strain relief element affixed to the proximal end of the shaft and to the distal end of the hub. Klima et al., however, teaches a strain relief element 22 (Fig 1) interconnected between a hub 16 (Fig 1) and a proximal end of a shaft 20 (Fig 1) for the purpose of providing a connection between the hub and the shaft (Col 2, Line 47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include a strain relief element, as taught by Klima et al., for the purpose of connecting the hub and shaft (Col 2, Line 47).

53. Claims 33, 36, 74, 75, 76, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US pat 5,616,137)/Stevens et al. (US Pat 5,916,193)/Savage et al. (WO 01/51116) in view of Mottola et al. (US Pat 6,179,816).

54. Re claim 33, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the microholes are radially distributed about the porous section uniformly and according to a gradient along a longitudinal axis thereof. Mottola et al., however, teaches microholes 34 (Fig 3) that are radially distributed (as seen in Fig 3) about a porous section uniformly (Col 3, Lines 43-46) and according to a gradient along a longitudinal axis thereof (Col 9, Lines 20-23) for the purpose of creating an even distribution of fluid (Col 9, Lines 22-23). Therefore, it would have been obvious to one

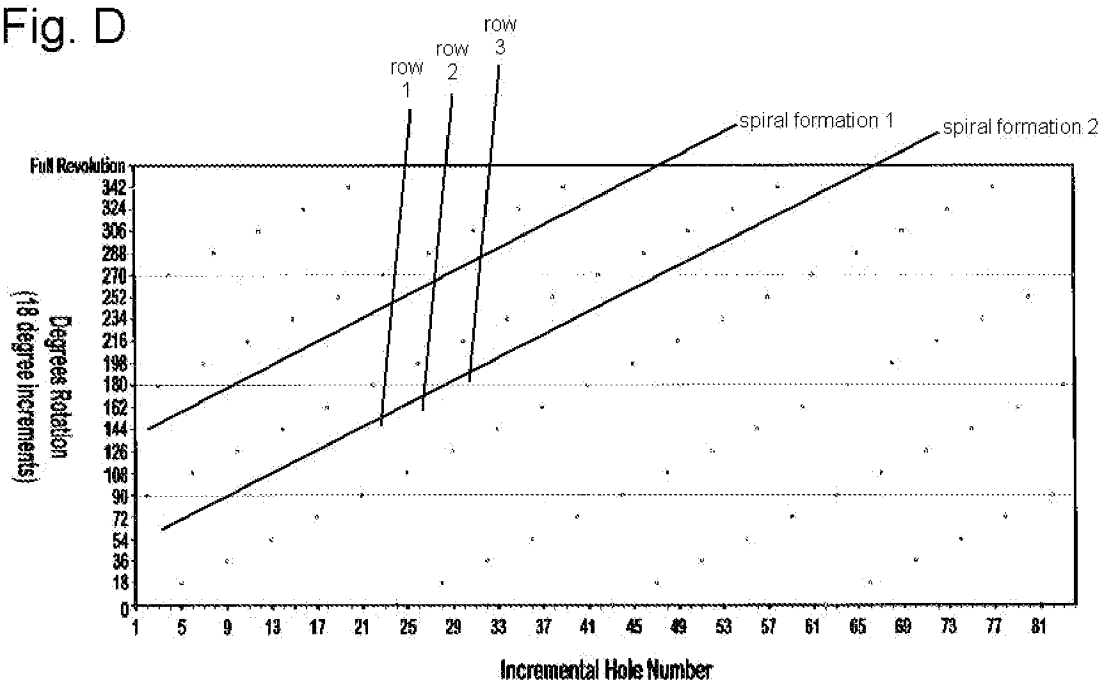
of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include microholes radially distributed uniformly and according to a gradient along a longitudinal axis, as taught by Mottola et al., for the purpose of crating an even distribution of fluid (Col 9, Lines 22-23).

55. Re claims 36 and 74, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the microholes are distributed about the porous section according to a pattern having a plurality of laterally-spaced spiral formations. Mottola et al., however, teaches microholes 34 (Fig 3) that are distributed about a porous section according to a pattern having a plurality of laterally-spaced spiral formations (as seen in Fig 3 and Fig 7; Col 3, Line 39) for the purpose of creating a complete dispersion of fluid (Col 3, Line 40). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include microholes distributed according to a pattern having a plurality of laterally-spaced spiral formations, as taught by Mottola et al., for the purpose of creating a complete dispersion of fluid (Col 3, Line 40).

56. Re claim 75, Lindsay/Stevens et al./Savage et al. disclose all the claimed features except that the porous section has two of said spiral formations each of which having a plurality of laterally-offset rows of microholes, with each of said rows in one of said spiral formations being diametrically opposite from a counterpart one of said rows in the other of said spiral formations. Mottola et al., however, teaches that the porous section (formed by microholes 34, Fig 3) has two of said spiral formations (best seen in Fig D below; Col 3, Line 39) each of which having a plurality of laterally-offset rows of

microholes (best seen in Fig D below) for the purpose of creating a complete dispersion of fluid (Col 3, Line 40). Mottola et al. does not explicitly teach that each of said rows in one of said spiral formations being diametrically opposite from a counterpart one of said rows in the other of said spiral formation but does teaches that the angles of spacing and inclination between holes can be modified (Col 4, Lines 42-64); a change in such angles could produce rows that are diametrically opposite from a counterpart row in the second spiral formation for the purpose of creating a complete dispersion of fluid (Col 3, Line 40). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al. to include two spiral formations having a plurality of laterally-offset row of microholes, as taught by Mottola et al., for the purpose of creating a complete dispersion of fluid (Col 3, Line 40).

Fig. D



57. Re claim 76, Lindsay discloses all the claimed features except that the predetermined angel by which the microholes of the porous section are inclined is approximately 0 degrees. Stevens et al., however, teaches microholes 666 (Fig 4J) perpendicular to the central axis (and thus being inclined at approximately 0 degrees; Fig 4J) for the purpose of providing flow ports to the catheter (Col 15, Lines 8-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay to include microholes inclined at approximately 0 degrees, as taught by Stevens et al., for the purpose of providing flow ports to the catheter (Col 15, Lines 8-9).

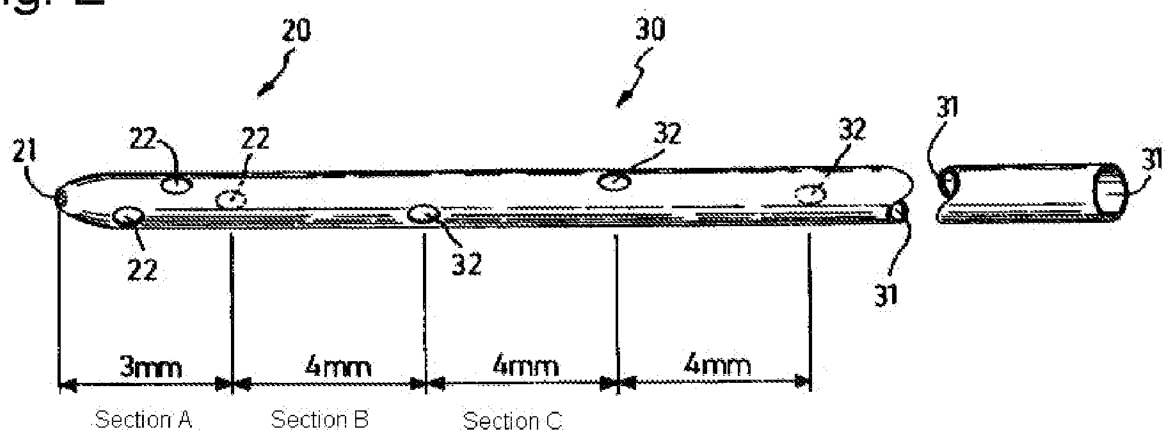
58. Re claim 77, Lindsay discloses that the catheter assembly is implemented as a flush-type catheter (Col 1, Lines 3-5).

59. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay (US pat 5,616,137)/Stevens et al. (US Pat 5,916,193)/Savage et al. (WO 01/51116)/Mottola et al. (US Pat 6,179,816) in view of Eldor (US Pat 5,800,407).

60. Re claim 34, Lindsay/Stevens et al./Savage et al./Mottola et al. disclose all the claimed features except that the microholes along the longitudinal axis are deployed in a plurality of sections of substantially equal length wherein the number of said microholes in each of said sections changes according to a linear progression. Eldor, however, teaches that the number of microholes 22, 32 (Fig 1) along the longitudinal axis are deployed in a plurality of sections A, B (best seen in Fig E below) of substantially equal length (as seen in Fig E below) wherein the number of said microholes in each of said sections changes according to a linear progression (1

microhole in section B, 3 microholes in section A as in Fig E below) for the purpose of injecting a desired stream of fluid (Col 4, Lines 49-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al./Mottola et al. to include microholes deployed in a plurality of sections having substantially equal length wherein the number of said microholes in each section changes according to a linear progression, as taught by Eldor, for the purpose of injecting a desired stream of fluid (Col 4, Lines 49-50).

Fig. E



61. Re claim 35, Lindsay/Stevens et al./Savage et al./Mottola et al. disclose all the claimed features except that the plurality of sections includes a proximal section having a fewest number of microholes, a middle section having double the number of microholes in said proximal section, and a distal section having triple the number of microholes in said proximal section. Eldor, however, teaches a proximal section C (best seen in Fig E above) having a fewest number of microholes (1 microhole as seen in Fig E below), a middle section B (best seen in Fig E above), and distal section A (best seen in Fig E above) having triple the number of microholes in the proximal section (3

microholes as seen in Fig E below) for the purpose of injecting a desired stream of fluid (Col 4, Lines 49-50). Eldor does not explicitly teach that the middle section has double the number of microholes in the proximal section but does teach that the number of total microholes may be altered (Col 4, Lines 44-50) thus making it obvious to add an additional microhole in the middle section so that it has double the number of microholes in the proximal section. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lindsay/Stevens et al./Savage et al./Mottola et al. to include three sections having different numbers of microholes, as taught by Eldor, for the purpose of injecting a desired stream of fluid (Col 4, Lines 49-50).

Response to Arguments

62. Applicant's arguments filed 3/23/2009 have been fully considered but they are not persuasive.

63. Applicant's arguments with respect to claims 63-69 that "the conical wall portion of claims 63-67 always remains an inseparable or indivisible structure" and therefore "the leaflets 662 [of Stevens et al.] cannot form a cone-shape at all, as they are by definition separated from each other", the examiner respectfully disagrees as no such feature (that the conical wall portion always remains an inseparable or indivisible structure) is in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is further noted that such leaflets can form a cone-shape as seen in Fig 4H and 4J.

64. Applicant’s arguments with respect to claims 1-77 that “the valve 660 of Stevens et al. must occupy either the closed or open position and no state in between”, the examiner respectfully disagrees as the valve inherently must occupy a multitude of positions while moving from the fully closed to the fully open position.

65. Applicant’s arguments with respect to claims 1-62 and 70-77 that “Lindsay is not a valve at all, merely a mechanism to diffuse a portion of the distally-directed blood flow radially outwardly into the aorta”, the examiner respectfully disagrees as a valve can be, by definition, a device for controlling the flow of a material; thus, diffuser 38 of Lindsay is indeed a "valve" as claimed.

66. Applicant’s arguments with respect to claims 1-62 and 70-77 that sideholes 42 of Savage et al. “are not microholes of the size claimed by Applicants”, the examiner respectfully points out that such size requirement is only claimed in dependent claims 20, 21, and 42-44 and, as indicated in the action above, is taught by Schwartz et al.

67. Applicant’s arguments with respect to claims 1-62 and 70-77 that Savage et al. teaches an increase in diameter of opening 44 at very high velocities and "thus teaches the opposite of Applicant's claims", the examiner respectfully disagrees as all claimed structure is taught by Lindsay and Stevens et al. and Savage is utilized to teach the balance of pressure in the vessel to remain stability.

Conclusion

68. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 7:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 3767

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763